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BHSF Research Matters

Newsletters

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1-2021

### Volume 2 Issue 1

Center for Research

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# Research Matters



*Elevating care through discovery.*

January 2021, Vol. 2, Iss. 1

## Message from Amy K. Starosciak, Ph.D.

Director of Outcomes Research, Center for Research

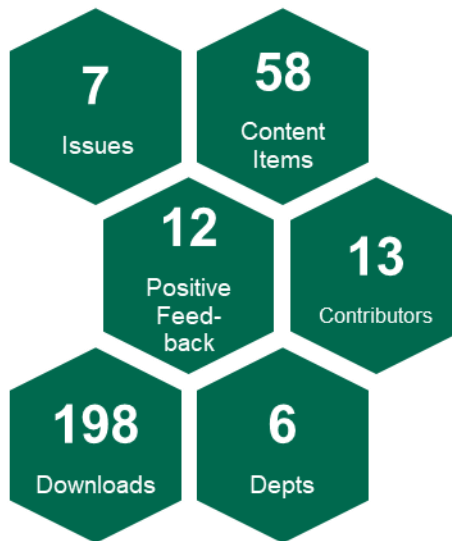
**H**appy holidays and happy New Year to the BHSF Research group! In this issue we look back over the year and contemplate the impressive changes that our research departments have undertaken to ensure that our patients and staff remain safe while participating in and conducting clinical research as well as celebrate some of the successes we have seen throughout the year.

It has been a year since the launch of the system-wide *Research Matters* newsletter in December 2019. On the right, here are some statistics from the first volume. Thanks to the editorial team for their dedication to this effort!

As we look at what is to come for *Research Matters*, **we are seeking new members to our editorial team — an Associate Editor and Editor-in-Chief.** As some of you may know, we bid farewell to Noah Zanville, Ph.D., RN, who left Baptist Health to become the Nurse Scientist Scholar at Mission Health in Asheville, NC overseeing their nursing research program. Also, I would like to give the Editor-in-Chief opportunity to someone who is passionate about research and connecting with the greater BHSF research community. **If you are interested** in joining the editorial team, please contact me at [amyst@baptisthealth.net](mailto:amyst@baptisthealth.net). Read back issues of the newsletter on the [Scholarly Commons](#).

It also has been one year since the launch of the BHSF Research Operations Lunch & Learn, that started in-person in January 2020 and has been taking place remotely since April. Check out page 5 for some stats on the Lunch & Learn and page 7 for the 2021 schedule.

Finally, with the COVID-19 pandemic still looming over us, we see hope in research and hope with the vaccine. The pandemic led to some **extraordinary and innovative changes** in our research departments, so check out pages 3 and 4 to see what **MCVI and Boca Raton research programs** have implemented for now and the future. With that, I wish everyone a happy and healthy New Year. Stay safe out there! And continue doing exceptional work.



*“Without data,  
you’re just  
another person  
with an opinion.”*

*—W. Edwards Deming—*

## Inside this issue

New Staff Updates.....	2
Marcus Neuroscience Instit...	2
COVID & MCVI Research.....	3
COVID & BRRH Research...	4
Lunch & Learn Dashboard....	5
New Article Alcove.....	6
Education.....	7
Compliance Corner.....	8

# New Staff Updates



**Catharina Chang-Martinez, Ph.D., MSN, RN, ARNP**  
Nurse Scientist  
Nursing & Health Sciences



**Claire P. Valdes, BSN, RN**  
Clinical Data Analyst  
Miami Neuroscience  
Institute Research



## MARCUS NEUROSCIENCE INSTITUTE

### Spotlight on Boca Raton Regional Hospital's Research Programs

Research at the [Marcus Neuroscience Institute](#) (MNI) at Boca Raton Regional Hospital integrates the practices of Neurology, Neurosurgery, and Neuro-oncology. Currently the trial portfolio includes research from pharmaceutical industry for Migraine, Parkinson's disease, Multiple Sclerosis, and Orthostatic Hypotension. Moreover, MNI participates in clinical trials through the [NIH StrokeNet](#), as well as collaborates with Duke University, University of Florida, Florida Atlantic University, and Scripps Research.

In addition to stroke and brain tumor trials, MNI offers a trial that evaluates cord tissue derived mesenchymal stem cells for treatment of acute respiratory syndrome (ARDS) in patients with COVID-19 infection. There have been two patients enrolled at MNI and overall enrollment of 10 patients through out all the participating sites. The institute is planning to open a research laboratory in 2021 to continue advancing stem cell research and expand its use to areas like stroke.

A highly trained and experienced group of physicians brings years of clinical and research experience to the Institute. The medical team consists of eight neurologists, including a neuro-oncologist and a neuro-intensivist, and five neurosurgeons. The institute Senior Research Nurse and the research administrative team work very closely with the clinical staff to enroll patients in clinical trials and evaluate new research opportunities to offer to our patients. —*Stephanie A. Boodram, Research Data Analyst, Office of Research Administration & Lynn Cancer Institute*

# EFFECTS OF COVID-19

## How the Pandemic Accelerated the Transformation of MCVI Research

At the Miami Cardiac & Vascular Institute (MCVI), the COVID-19 pandemic changes have accelerated an innovative transformation for the conduct of research trials. Here, we share our experience hoping to offer suggestions to navigate these changes for successful outcomes.

Our sponsors, investigators, clinical research professionals, clinical trial coordinators, managers, and nurses report positive experiences with these COVID-related adjustments. These measures are aiming to help reduce the spread of COVID-19 and require the integration and collaboration of sites, sponsors, and other BHSF departments to reimagine how to safely conduct clinical trials in a remote and technology-based environment.

This was no small task, as adopting new technology requires administrative, regulatory, and process changes. These changes also are part of a sustainable model so we do feel some of the measures we have introduced in 2020 to mitigate COVID-19 disruptions are here to stay.

- ◆ **Removed unnecessary site visits.** Restrictions implemented for outside vendors, monitors, or clinical research associates.
- ◆ **Established several new partnerships** to study COVID in close collaboration with the David Geffen School of Medicine at UCLA and the Icahn School of Medicine at Mount Sinai in New York City. We have engaged in 5, very innovative and distinctive COVID trials, including filing of our own MCVI formal IND application with the FDA to study the effects of COVID in the myocardium and all open studies are actively enrolling patients.
- ◆ Adopted remote monitoring, remote review/verification of research participant data, remote site qualification, and remote site initiation visits.
- ◆ **Reduced in-person participant interaction** for non-clinical related tasks.
- ◆ **Incorporated phone calls** and remote checks for participants.
- ◆ Protect patient and staff with changes such as: remote consents, when possible conducting remote study visits, and streamlining the clinical trial participation process.
- ◆ Created **COVID Standard Operational Procedures** and new policies for addressing research activities during potential similar emergencies at our workplace.
- ◆ Adopted routine inspection suspension as determined by the FDA.
- ◆ Remote document creation, management, and collection.
- ◆ Continued strict study oversight and compliance adherence.
- ◆ Allowed **offsite work when possible** and in accordance with BHSF policies.
- ◆ Began conducting all committee meetings virtually.

We do hope these suggestions help, we do feel that now more than ever is crucial for all BHSF research Centers of Excellence to communicate with each other and share projects, collaborations and recommendations for keeping sites running in accordance with the highest scientific and regulatory standards. All ideas and tips on virtual check-ins with patients, how to incorporate at-home follow up visits or even suggestions on where to cut expenses to save money, working together could help find ways to make it through this pandemic.

For MCVI, the strength has been the consistently solid team structure and the intensely cohesive nature of our group. MCVI research is very unified; that has made the difference.

—Raul Herrera, M.D., Director of Research and Outcomes, Miami Cardiac & Vascular Institute

# EFFECTS OF COVID-19

## Longer Term Effects on Research at Boca Raton Regional Hospital

Conducting clinical trials research is always a frenetic endeavor. This year we added a wholly unexpected variable to this complex equation when the COVID pandemic hit our area. Some industries had no choice but to put operations on hold and hunker down to maintain the safety of their employees and the public. Our choice was clear; we had to continue providing access to clinical trials that were opened before COVID for the continuity of care for our patients. To maintain that continuity, we had to adapt our processes to ensure the safety of our research staff and the patients on our trials. The research community is fairly close knit and we become very familiar with our clinical trial sponsor representatives as well as our regulatory contacts. These groups came together to ensure the continued access to clinical trials that is so critical for our patients' care.

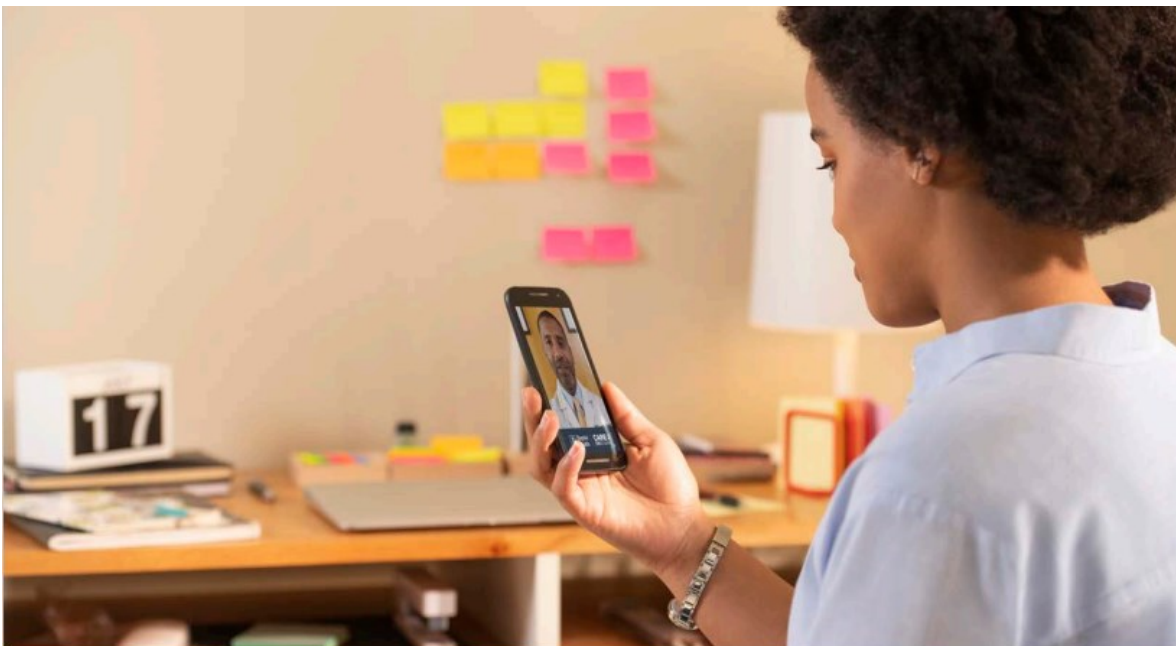
At Boca Raton Regional Hospital, these changes included:

- ◆ Implementing sponsors' COVID-specific protocol changes to minimize disruptions in trial conduct including remote patient

visits wherever possible. This change complemented our institution's restrictions on visits to minimize potential patient exposure.

- ◆ Regulatory bodies (e.g., IRBs) allowing for quick submission and turnaround of protocol and site amendments to accommodate institutional, local, state and federal restrictions. These changes allowed fluidity to implement changes to maintain continuity of clinical trials.
- ◆ Innovation by our study coordinators to ensure the patient experience and care was minimally impacted. For example, one of the toughest changes came with restricting patients from having their family members accompany them as normally would have been the case due to COVID restrictions. The coordinators adapted to the change and conducted the patient visits with the family member on video call to make the visit as close to "normal" as possible.

—Ileana Vargas, Research Regulatory Specialist, Office of Research Administration & Lynn Cancer Institute



# BHSF RESEARCH LUNCH & LEARN

## 2020 Attendees Survey Dashboard

We successfully completed a year of Research Lunch & Learns, of which April-December were virtual. In April, we converted to REDCap to document attendance and survey attendees to ensure that we were providing interesting and useful information for to our staff. A total of 290 people attended in 2020 for an average of 24 people/session. There were 80 unique attendees from Boca Raton Regional Hospital, Center for Research, IRB, MCI Office of Clinical Trials Office, MCI Clinical Operations Support, MCI Protocol Support Laboratory and Biorepository, MCVI Research & Outcomes, MNI Research (South), MOSMI/UHZ Research, and Nursing & Health Science Research.

The topics and order were developed based on a Needs Assessment Survey sent to research operations and regulatory staff in December 2019. Respondents selected the top three topics they were interested in. However, with the COVID-19 pandemic, three relevant topics were selected for April through June, and resumed with the original order in July. The dashboard from the attendee survey is provided below. A new Needs Assessment Survey was sent in December 2020 with added topics and the new set of topics for 2021 can be found on Page 7.

—Amy K. Starosciak, Ph.D., Director of Outcomes Research, Center for Research

### BHSF Research Operations Lunch & Learn



Total Attendees

**290**

Total Sessions

**12**

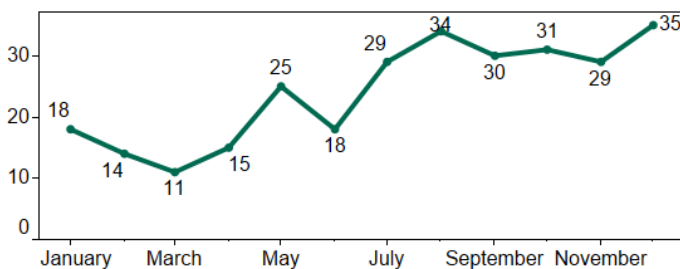
Avg Attendees/Session

**24**

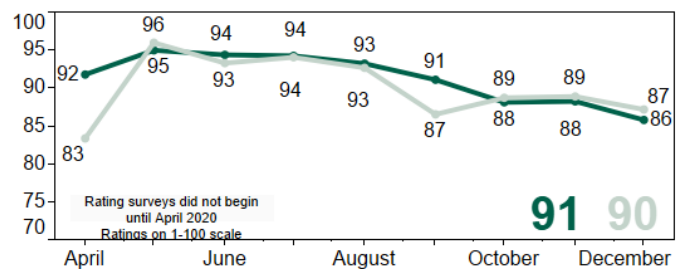
Total Unique Attendees

**80**

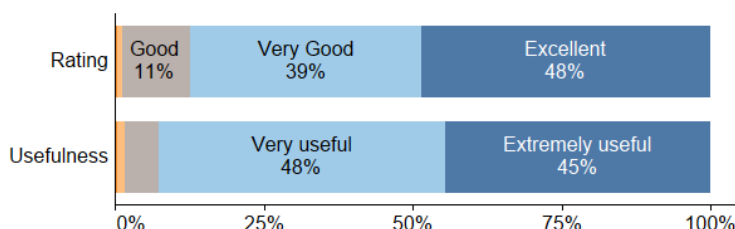
Number of Attendees by Date



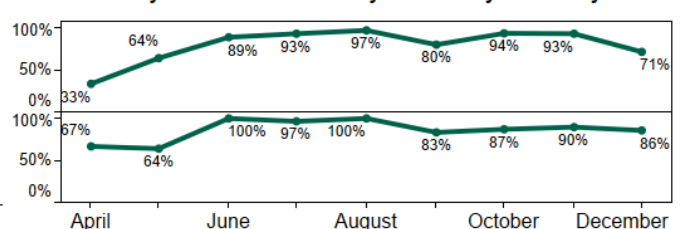
How Likely Were Attendees to Attend a Future Session or Recommend the Series to a Colleague



Continuous Scale



"Excellent/Very Good" and "Extremely Useful/Very Useful" by Month





# New Article Alcove

Explore our new publications!

\*Alvarez R, ^China AV, ^Braley AE, ^Majid S, **Patel K, Segui D, Starosciak AK, Gonzalez-Arias S** (2021) Cortical screw fixation using CT-navigation coupled with real-time electrophysiological monitoring of individual screw placement for unstable degenerative lumbar spondylolisthesis. *Interdisc Neurosurg* 24:101051. [Find it here!](#) (\*Current FIU Medical Student, ^Former FIU Medical Student)

Appunni S, **Rubens M**, Ramamoorthy V, Anand V, Khandelwal M, **Saxena A, McGranaghan P, Odia Y, Kotecha R**, Sharma A (2021) Lumican, pro-tumorigenic or anti-tumorigenic: A conundrum. *Clin Chim Acta* 514: 1-7. [Find it here!](#)

Balduzzi A, van der Heijde N, Alsedi A...**Asburn HJ**, et al. (in press) Risk factors and outcomes of conversion in minimally invasive distal pancreatectomy: A systematic review. *Lagenbecks Arch Surg* [Find it here!](#)

Huang J & **Mehta M** (in press) Can proton therapy reduce radiation-related lymphopenia in glioblastoma? *Neuro Oncol* [Find it here!](#)

Kittipibul V, Singh H, Flowers R, **Chaparro S** (2020) The utility of CardioMEMS in left ventricular assist device patients with gastrointestinal bleeding. *J Cardiol Cases* 22:276-279. [Find it here!](#)

**Kotecha R**, Dea N, Detsky JS, Sahgal A (2020) Management of recurrent or progressive metastases : Reirradiation techniques and surgical principles. *Neurooncol Pract* 7(Suppl 1):i45-i53. [Find it here!](#)

Mayock DE, Xies Z, Comstock BA...on behalf of the PENUT Trial consortium (includes **Perez JE, Diaz Barbosa M, Bombino S**) (2020) High-dose erythropoietin in extremely low gestational age neonates does not alter risk of retinopathy of prematurity. *Neonatology* 28: 1-8. [Find it here!](#)

Mekhail N, Deer TR, Kramer J,...**Levy RM** (2020) Paresthesia-free dorsal root ganglion stimulation: An ACCURATE study sun-analysis. *Neuromodulation* 23(2): 185-195. [Find it here!](#)

Mossahebi S, **Sabouri P**, Chen H, et al. (2020) Initial validation of proton dose calculations on SPR images from DECT in treatment planning system. *Int J Part Ther* 7(2):51-61. [Find it here!](#)

Oni E, Ogunmoroti O, Allen N...**Veledar E**, Nassir K (in press) Life's Simple 7 and non-alcoholic fatty liver disease: The multi-ethnic study of atherosclerosis. *Am J Med* [Find it here!](#)

Shaw LJ, Blankstein R, Bax JJ...**Cury R**, et al. (in press) Society of Cardiovascular Computed Tomography / North American Society of Cardiovascular Imaging e Expert Consensus Document on Coronary CT Imaging of Atherosclerotic Plaque. *J Cardiovasc Comput Tomogr* [Find it here!](#)

**Yagnik GP, Santos ED, Rothfeld AA, Uribe JW, Cohn TM** (2021) Spanish translation and cross-language validation of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form. *J Shoulder Elbow Surg* 30: 151-157. [Find it here!](#)

**Don't forget to check out the new issue of the Nursing & Health Sciences Research Journal. [Find it here!](#)**

**Explore more publications from the Baptist Health Institutional Repository**

- [Center for Advanced Analytics](#)
- [Center for Research](#)
- [Christine E. Lynn Heart & Vascular Institute](#)
- [Christine E. Lynn Women's Health & Wellness Institute](#)
- [Eugene M. & Christine E. Lynn Cancer Institute](#)
- [Marcus Neuroscience Institute](#)
- [Miami Cancer Institute](#)
- [Miami Cardiac & Vascular Institute](#)
- [Miami Neuroscience Institute](#)
- [Miami Orthopedics & Sports Medicine Institute](#)

Did we miss your publication?

Please send it to:

[library@baptisthealth.net](mailto:library@baptisthealth.net)

## **Tuesdays 12:00 to 1:00 pm**

Invite was sent out to Research Operations & Regulatory teams. Certificates provided.

Because of the COVID-19 pandemic, we will be doing Zoom™ meetings only until further notice.

[Click here](#) or go to [baptisthealth.zoom.us](https://baptisthealth.zoom.us)

Meeting ID: 958 8490 1869  
Password: 861787



Date	Topic
Tuesday, January 12th	Consent Best Practices
Tuesday, February 9th	Investigator Initiated Trials
Tuesday, March 9th	Study Startup
Tuesday, April 13th	Audit Preparation
Tuesday, May 11th	Clinical Trial Agreement (CTA) Basics
Tuesday, June 8th	Research Finance Basics
Tuesday, July 13th	Appraisal of Statistical Methods in Research by Emir Veledar, Ph.D.
Tuesday, August 10th	Principles of Good Clinical Practice
Tuesday, September 14th	Participant Safety
Tuesday, October 12th	Preventing Noncompliance
Tuesday, November 9th	Participant Recruitment
Tuesday, December 14th	Study Documentation

## **UPCOMING CONFERENCES**

by Nursing & Clinical Research Organizations

Onsemble—April 18-22, 2021, Phoenix, AZ  
<https://conference.onsemble.net/>

ACRP— May 14-17, 2021, Toronto, Canada  
<https://acrpnnet.org/event/acrp-2021-annual-conference/>

SOCRA—September 24-26, 2021, Denver, CO  
<https://www.socra.org/annual-conference/future-annual-conference-dates/>

Nursing World Conference—October 18-21, 2021, **Virtual**  
<https://nursingworldconference.com/>

ANCC Magnet & Pathway—November 11-13, 2021, Atlanta, GA  
<https://www.magnetcon.org/>





## Center for Research

### MISSION

To serve as a research hub for elevating care through discovery for the diverse community we serve by using a shared service model that capitalizes on synergies created through a collaborative intellect.

### VISION

In alignment with the strategic goals of Baptist Health South Florida, and within the context of a sustainable business model, the Center facilitates the development and dissemination of knowledge with the goals of providing continued excellence in patient care for the diverse multicultural community of South Florida.

## Research Compliance Corner

Here at Research Compliance, we recognize the importance of communicating the most accurate and up-to-date information about trials offered at Baptist Health to our customers. As such, the Center for Research provides research teams guidance and assistance when registering clinical trials and reporting their results on [ClinicalTrials.gov](https://clinicaltrials.gov). *“ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.”*<sup>1</sup> Upon request, we will also provide quality checks (QCs) of any records prior to submitting them with the aim to reduce the number of revisions required. In addition, we also provide guidance regarding whether a study should be registered in ClinicalTrials.gov or not. All questions and/or requests may be submitted via email. Please register all BHSF clinical trials in ClinicalTrials.gov under the Institution name, BaptistHSF, to allow the institution’s administrators access to the records. <sup>1</sup> <https://clinicaltrials.gov/ct2/help/for-patient>



Do you have any questions or topics you would like for us to cover regarding conflicts of interest, compliance review, or billing compliance process? If so, contact us directly for all Research Compliance matters!

Heather Osorio, Research Compliance & Billing Administrator, [ResearchCompliance@baptisthealth.net](mailto:ResearchCompliance@baptisthealth.net)

## UPCOMING IRB DATES

### BHSF IRB

Full Board Committee Meeting: **Tuesday, January 26th**

Submission Deadline for February Meeting: **Monday, January 25th**

### MCI IRB

Full Board Committee Meeting: **Monday, February 1st**

## EDITORIAL STAFF

Amy K. Starosciak, Ph.D., Center for Research, Editor-in-Chief  
Stephanie Boodram, BRRH Lynn Cancer Institute  
Nicholas K. Chow, Pharm.D., BCOP, MCI Pharmacy  
Ileana Vargas, BRRH Office of Research Administration

To contribute to this newsletter, please contact Dr. Amy Starosciak at [amyst@baptisthealth.net](mailto:amyst@baptisthealth.net) or x79546.



**Baptist Health South Florida**  
Center for Research